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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,858	10/06/2000	Peter Beetham	PM49317/272063	9880

7590 11/19/2003
Saliwanchik, Lloyd & Saliwanchik
John M. Sanders
2421 N.W. 41st. Street
Suite A-1
Gainesville, FL 32606

EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/680,858

Applicant(s)

BEETHAM ET AL.

Examiner

David H Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24 and 28-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24 and 28-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10/03 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 28 August 2003 has been entered.
2. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claim 36 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim is indefinite because it is unclear if the claim is directed to an isolated plant microspore or to a regenerated plant containing a genomic mutation, hence the metes and bounds of the invention are unclear.
5. Claims 24 and 28-32 remain rejected and claims 33-38 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

Art Unit: 1638

the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 28 April 2003. Applicant's arguments filed 28 August 2003 have been fully considered but they are not persuasive.

Applicant's argument as directed to U.S Patents 3,565,350 and 5,731,181 on pages 3-4 of the 28 May 2003 response are not found to be persuasive because each application for patent is examined upon its own merits.

Applicant argues that the specification makes it perfectly clear to one of ordinary skill in the art how to practice the presently claimed invention and that limiting the Applicants to only the MDONs specified in the specification would be akin to depriving the applicants of the value of their invention (page 4 of the 28 August 2003 response). This argument is not found to be fully persuasive because the instant claims are directed to any plant microspore comprising any mixed duplex oligonucleotide, and as such Applicant has not adequately described the invention as broadly claimed. See *Brenner v. Manson*, 383 U.S. 519 (1966), which states "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field."

6. Claims 24 and 28-32 remain rejected and claims 33-38 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 28 April 2003.

Applicant's arguments filed 28 August 2003 have been fully considered but they are not persuasive.

Applicant argues that gene repair, in and of itself, was known in the art at the time of the present priority date. Applicant also argues that the present claims are [is] similar to the scope of the Kmiec '350 and Kmiec '181 patent claims in that they do not specify a specific gene or a specific oligonucleotide (paragraph spanning pages 6-7 of the Remarks). As directed to the Kmiec patent claims, the Examiner reiterates that each application is examined upon its own merits. As directed to the instant application, Applicant's have failed to teach one of skill in the art at the time of Applicant's invention how to make and use the invention within the full scope of the claims. The instant claims are directed to any plant microspore comprising any mixed duplex oligonucleotide (claim 24), any mutated plant microspore that comprises any genomic mutation introduced by a mixed duplex oligonucleotide (claim 30), any isolated plant microspore which comprise a genomic mutation introduced by a mixed duplex oligonucleotide (claim 33) and to any plant regenerated from said isolated plant microspore (claim 37). As previously stated by the Examiner, the art teaches that one of skill in the art at the time of Applicant's invention could not readily predict that a specific mixed duplex oligonucleotide would introduce the desired mutation without

empiric evidence. Kochevenko *et al* (Plant Physiology, 132:174-184, 2003) teach that one cannot readily predict that a specific mixed duplex oligonucleotide will produced the desired nucleotide base change in the genomic DNA of a plant without a reduction to practice and that in several instances unpredicted nucleotide base changes occurred (see Table 1 on page 179). Kochevenko *et al* also teach that the application of mixed duplex oligonucleotide mediated gene repair techniques in plants produces semitargeted mutations or mutations other than those intended in the expected nucleotide (page 175, left column, 1st paragraph). Hence, it remains the Examiner's opinion that it would required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to make and use any plant microspore comprising any mixed duplex oligonucleotide as broadly claimed.

Claim Rejections - 35 USC § 102

7. Claims 30-32 remain rejected and claims 36-38 are rejected under 35 U.S.C. § 102(a) as being anticipated by Hawkes *et al* (WO 98/54330, published 3 December 1998, priority date 28 May 1997). This rejection is repeated for the reason of record as set forth in the last Office action mailed 28 April 2003. Applicant's arguments filed 28 August 2003 have been fully considered but they are not persuasive.

Claim 36 is included in this rejection because of the issue of indefiniteness as outlined above, and has been interpreted as being directed to a plant that contains a genomic mutation introduced by a mixed duplex oligonucleotide.

Applicant argues that Hawkes *et al* teach the use of gene repair with pollen and that pollen and microspores are distinct tissues (page 7, 2nd paragraph of the Remarks).

This argument is not found to be persuasive because the instant claims are directed to mutated plant microspores and plants and seed of said plants comprising a mutation, as such the instant claims would be indistinguishable from those plants, seeds or parts thereof disclosed by Hawkes *et al* (see claim 18). See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claim Rejections - 35 USC § 103

8. Claims 24 and 28-32 remain rejected and claims 33-38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kmiec (US Patent 5,731,181, filed 17 June 1996) in view of Fennell *et al* (1992, Plant Cell Reports 11:567-570). This rejection is repeated for the reason of record as set forth in the last Office action mailed 28 April 2003. Applicant's arguments filed 28 August 2003 have been fully considered but they are not persuasive.

Applicant argues that plant transformation as taught by Fennell *et al* can be considered in many respects to be the antithesis of plant transformation which involves the insertion of genes into plants while gene repair uses small oligonucleotides that are chemically different from the large vectors used in transformation and which are incapable of being incorporated into the host DNA. Applicant also argues that nothing the microspore transformation methodology would indicate predictability or likelihood of success of the presently claimed microspore gene repair process (paragraph spanning pages 5-6 of the Remarks). This argument is not found to be persuasive because as

Art Unit: 1638

previously stated by the Examiner, Kmiec teaches that the mixed duplex oligonucleotide can be introduced into a cell using a wide variety of techniques known in the art at the time of Applicant's invention including electroporation and liposome mediated fusion (see column 1, lines 29-33). The method of introducing polynucleotides as taught by Fennell *et al* would have been considered a reasonable method as suggested by Kmiec, and that one of ordinary skill in the art would have been motivated to use the method of Fennell *et al* because they teach that using microspores has the advantage as useful for producing haploid plants that can be used to produce homozygous diploids (see page 567, right column, end of Introduction). Finally, one of ordinary skill in the art would have had a reasonable expectation of success given the teachings of Fennell *et al* in introducing a mixed duplex oligonucleotide into any plant microspore and producing a genetic mutation as suggested by the teachings of Kmeic.

Conclusion

9. This Office action is non-final.
10. No claims are allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.
17 November 2003

AU 1638